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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,520	11/26/2003	Yves Faisandier	8707.2170	8916

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EXAMINER

NASSER, ROBERT L

ART UNIT	PAPER NUMBER
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3735

DATE MAILED: 10/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/724,520

Applicant(s)

FAISANDIER, YVES

Examiner

Robert L. Nasser

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant has disclosed that there is a relationship between the index and systolic pressure and that the index is determinable from the second cardiac sound. However, applicant has not disclosed how the index is calculated and how it is converted to a measure of pressure. As such, the invention is not enabled.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a Patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3, 8, 11, 14, and 19 are rejected under 35 U.S.C. 102(a) as being anticipated by Xu et al, US 6,368,283 B1, hereinafter referred to as Xu.

With respect to claim 1, Xu et al has a first sensor 6 for detecting acoustic signals and producing a electric phonocardiographic signal related to heart sounds, a processor 14 that isolates the second cardiac sounds S2, and a processor (means for) determining a parameter of the sounds, i.e. A2(t) and determining an index NSI

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therefrom, where the index is indicative of blood pressure. As to Claim 2, Xu teaches that "preferably the first extracting means, the second extracting means, the third extracting means, the correlating means, the measuring means, the second producing means and the estimating means are embodied by the computer (12)." [Column 7, Lines 22-25] It is inherent that the computer has a memory and that the phonocardiograph signal must be stored/recorded at least while it is being processed. Claims 3 and 14 are rejected in that the parameter is a variation of the derivative of the phonocardiographic signal (see previous office action dated 2/10/2006). Claims 8 and 19 are rejected in that Xu discloses "a filtering means for low-pass filtering the signal obtained" (means for low pass filtering the determined phono-arterial index) [Column 8, Lines 25-26]. Claim 11 is rejected in that the system is calibrated against an absolute blood pressure measurement.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 5, 15, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu in view of Schulhauser et al, US 6,869,404 B2, hereinafter referred to as Schulhauser. As to Claim 4, Xu discloses the claimed invention as described in Paragraphs 3-4 of this action except for wherein the analyzing means further comprises means for applying a weighted value to said at least one parameter, said weighted value being variable from one vibratory profile to another. Schulhauser teaches an

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apparatus and method of chronically monitoring heart sounds for deriving estimated blood pressure. Schulhauser teaches that "based on the best fit analysis, a weighted predicted blood pressure value is determined for each spectral variable." Furthermore according to Equation (1) of Schulhauser, "wherein $WBP(P_i)$ is the weighted predicted blood pressure based on the i th spectral variable, P_i ; TSW is the total significance weighting, for the linear regression analysis of all spectral variables, and a and c ; are the x coefficient and constant determined by the linear regression of P ." [Column 13, Lines, 14-30] Schulhauser solves the same problem of Xu (estimating blood pressure using the second heart sound), and discloses a specific method of analysis towards estimating blood pressure based on the vibratory profile of the second heart sound. Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention to modify Xu to include an analysis as disclosed by Schulhauser for estimating blood pressure on the basis of the second heart sound of the heart.

Claims 5, 15, and 16 are rejected as being unpatentable over Xu in view of Schulhauser as discussed above.

Claims 6, 13, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu et al. Claims 6 and 17 are rejected in that the examiner takes official notice that it is well known in the medical field to provide two sensors and take the average of the signals, to avoid errors caused by anomalous readings. Hence, it would have been obvious to modify Xu to use two sensors, to improve the accuracy of measurement. Claim 13 is rejected in that the examiner takes official notice that it is well known to vary

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a therapy of control a therapy (such as medicine delivery) when a blood pressure reading is abnormal. Hence, it would have been obvious to modify Xu to deliver medication when the NSI indicates that blood pressure is abnormal.

Claim 9 and Claim 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu in view of Greenberger, US 5,492,129. Xu lacks means for evaluating a respiratory frequency of said patient, wherein said means for low-pass filtering further comprising means for adaptive filtering at a variable cutoff frequency, and means for adjusting said variable cutoff frequency at the time of analysis. Greenberger discloses "a noise reducing stethoscope for placement on the body to detect internal body sounds" [Abstract]. Greenberger " further teaches "a high pass filter can therefore be used effectively to separate the respiration sounds from the cardiac sounds..., the cutoff frequency should be variable so that the user can trade off between the level of cardiac sounds heard and the amount of low frequency respiration sounds that are filtered out." [Column 7, Lines 65+ and Column 8, Lines 1-6] since the apparatus of Greenberger is capable of solving the same problem of filtering respiratory noise during detection of internal body sounds, it would have been obvious to one with ordinary skill in the art at the time of the invention to modify the Xu to incorporate the variable cutoff filter of Greenberger.

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Claims 7, 10, 12, and 18 would be allowable if the rejection under 35 U.S.C 112, first paragraph were overcome and if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 7 and 18 define over the art in that none of the art has the means to detect different body positions, as claimed. Claim 10 defines over the art in that none of the art determines the filter gain base don't be phase of the respiratory cycles. Claim 12 defines over the art in that none of the art also determines an ecg based on the index.

Applicant's arguments filed 8/9/2006 have been fully considered but they are not persuasive.

Applicant has asserted in footnote 1 that the splitting interval does not correspond to the index of applicant's claims. Applicant has given no reasons to support this conclusion. It is the examiner's position that applicants index is converted to pressure by applying a function to the index and that the same is true of the splitting interval in Xu. Hence, it is the examiner's position that the splitting interval is an index.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is 571 272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert L. Nasser
Primary Examiner
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RLN
October 10, 2006